UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., and JANSSEN PHARMACEUTICA N.V., *Plaintiffs,* v. INDCHEMIE HEALTH SPECIALTIES PVT. LTD. and ALKEM LABORATORIES LTD. *Defendants.*	Civil Action No. _____

COMPLAINT

Plaintiffs Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and Janssen Pharmaceutica N.V. (collectively, "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing of Abbreviated New Drug Applications ("ANDAs") by Defendants Indchemie Health Specialities Pvt. Ltd. ("Indchemie") and Alkem Laboratories Ltd. ("Alkem") with the United States Food and Drug Administration ("FDA") for approval to manufacture and sell generic versions of Plaintiffs' Bystolic® drug products prior to the expiration of U.S. Patent No. 6,545,040 (the " '040 Patent").

PARTIES

2. Plaintiff Forest Laboratories, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 909 Third Avenue, New York, NY 10022.

3. Plaintiff Forest Laboratories Holdings, Ltd. is a corporation organized and existing under the laws of the Ireland, with a place of business at Milner House, 18 Parliament Street, Hamilton HM 11, Bermuda (referred to herein, together with Forest Laboratories, Inc., as "Forest").

4. Plaintiff Janssen Pharmaceutica N.V. is a corporation organized and existing under the laws of Belgium, with its principal place of business at Turnhoutseweg 30, B2340 Beerse, Belgium.

5. On information and belief, Defendant Indchemie is an Indian company having a place of business at 510, Shah & Nahar Industrila Estate, Dr. E. Moses Road, Worli-Mumbai 400018, India.

6. On information and belief, Indchemie manufactures and sells various generic drug products and regularly conducts business throughout the United States, including in the State of Illinois.

7. On information and belief, Defendant Alkem is an Indian company having a place of business at Alkem House, Devashish, Senapati Bapat Marg, Lower Parel (West), Mumbai 400013, Maharashtra, India.

8. On information and belief, Alkem manufactures and sells various generic drug products and regularly conducts business throughout the United States, including in the State of Illinois.

JURISDICTION AND VENUE

9. This action for patent infringement arises under 35 U.S.C. § 1 *et seq.* generally, and 35 U.S.C. § 271(e)(2) specifically.

10. This action arises under the patent laws of the United States of America, and this Court has jurisdiction over the subject matter of this dispute pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

12. This Court has personal jurisdiction over each of the Defendants by virtue of their consenting to such jurisdiction in a February 21, 2012 email to Plaintiffs from counsel for Indchemie and Alkem, Imron T. Aly, of the Chicago office of Winston and Strawn LLP, and by letters of February 3, 2012 authorizing Mr. Aly to accept service of process on behalf of Indchemie and Alkem, pursuant to 21 C.F.R. § 314.95(c)(7).

BACKGROUND

13. Bystolic® contains nebivolol hydrochloride (a beta-adrenergic blocking agent or "beta blocker"). According to its approved label, Nebivolol is a racemate composed of d-Nebivolol and l-Nebivolol with the stereochemical designations of [SRRR]-nebivolol and [RSSS]-nebivolol, respectively. Bystolic® "is indicated for the treatment of hypertension, to lower blood pressure."

INFRINGEMENT OF U.S. PATENT NO. 6,545,040

14. Plaintiffs incorporate each of the preceding paragraphs 1-13 as if fully stated herein.

15. On April 8, 2003, the United States Patent and Trademark Office ("USPTO") issued the '040 Patent to Janssen Pharmaceutica N.V. A true and correct copy of the '040 Patent is attached hereto as **Exhibit A**. The '040 Patent was submitted to the USPTO for *ex parte* reexamination on January 26, 2007. On February 17, 2009, the USPTO issued an *Ex Parte* Reexamination Certificate for the '040 Patent, attached hereto as part of **Exhibit A**, stating that

"no amendments have been made to the patent," and that the "patentability of claims 1-6 is confirmed."

16. Plaintiff Janssen Pharmaceutica N.V. is the assignee of the '040 Patent.

17. Plaintiff Forest is the exclusive licensee of the '040 Patent. Plaintiff Forest holds New Drug Application ("NDA") No. 021-742 for Bystolic® brand nebivolol hydrochloride tablets.

18. Forest is the exclusive distributor of Bystolic® in the United States.

19. Plaintiffs own all rights, title and interest in the '040 Patent, including all rights needed to bring this action in Plaintiffs' own names.

20. Bystolic® and its use in the treatment of hypertension are covered by one or more claims of the '040 Patent, and the '040 Patent has been listed in connection with Bystolic® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations,* which is referred to as the "Orange Book," as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" Bystolic®.

21. Indchemie, by its counsel, Winston & Strawn LLP, sent a letter to Plaintiffs, dated February 3, 2012 (the "Indchemie Notice Letter"), notifying Plaintiffs of its submission to the FDA of ANDA No. 203828 for Indchemie's generic nebivolol hydrochloride tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg, drug products that are generic versions of Bystolic® ("Indchemie's ANDA Products").

22. The purpose of the submission of the ANDA was to obtain permission under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use,

offer for sale, and/or sale of Indchemie's ANDA Products prior to the expiration of the '040 Patent. Plaintiffs received the Indchemie Notice Letter on or around February 3, 2012.

23. This action is being commenced before the expiration of forty-five days from the date of receipt of the Indchemie Notice Letter.

24. In the Indchemie Notice Letter, Indchemie also notified Plaintiffs that, as a part of its ANDA, Indchemie had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '040 Patent. On information and belief, Indchemie submitted ANDA No. 203828 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '040 Patent is invalid and/or will not be infringed by the manufacture, use, offer for sale, or sale of Indchemie's ANDA Products.

25. Indchemie's ANDA Products are covered by one or more claims of the '040 Patent.

26. Indchemie's filing of ANDA No. 203828 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Indchemie's ANDA Products before the expiration date of the '040 Patent is an act of infringement of the '040 Patent, under 35 U.S.C. § 271(e)(2)(A).

27. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Indchemie's ANDA Products would infringe one or more claims of the '040 Patent.

28. On information and belief, the use of Indchemie's ANDA Products in accordance with and as directed by Indchemie's proposed labeling for that product would infringe one or more claims of the '040 Patent.

29. On information and belief, unless enjoined by this Court, Indchemie intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Indchemie's ANDA Products with its proposed labeling immediately and imminently upon approval of ANDA No. 203828.

30. On information and belief, unless enjoined by this Court, Indchemie plans and intends to, and will, actively induce infringement of the '040 Patent when its ANDA No. 203828 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

31. Indchemie had knowledge of the '040 Patent when it submitted ANDA No. 203828.

32. On information and belief, Indchemie knows that Indchemie's ANDA Products and its proposed labeling are especially made or adapted for use in infringing the '040 Patent, and that Indchemie's ANDA Products and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, unless enjoined by this Court, Indchemie plans and intends to, and will, contribute to the infringement of the '040 Patent immediately and imminently upon approval of ANDA No. 203828.

33. The foregoing actions by Indchemie constitute and/or will constitute infringement of the '040 Patent, active inducement of infringement of the '040 Patent, and/or contribution to the infringement by others of the '040 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

34. On information and belief, Indchemie acted without a reasonable basis for believing that it would not be liable for infringing the '040 Patent, actively inducing infringement of the '040 Patent, and/or contributing to the infringement by others of the '040 Patent.

35. Unless Indchemie is enjoined from infringing the '040 Patent, actively inducing infringement of the '040 Patent, and/or contributing to the infringement of the '040 Patent, Plaintiffs will suffer irreparable injury.

36. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 203828 to be a date which is not earlier than December 17, 2021, the current expiration date of the '040 Patent, or any extension of that expiration date that might arise after the filing of this Complaint.

37. Alkem, by its counsel, Winston & Strawn LLP, sent a letter to Plaintiffs, dated February 3, 2012 (the "Alkem Notice Letter"), notifying Plaintiffs of its submission to the FDA of ANDA No. 203741 for Alkem's generic nebivolol hydrochloride tablets, 2.5 mg, 5 mg, 10 mg, and 20 mg, drug products that are generic versions of Bystolic® ("Alkem's ANDA Products").

38. The purpose of the submission of the ANDA was to obtain permission under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Alkem's ANDA Products prior to the expiration of the '040 Patent. Plaintiffs received the Alkem Notice Letter on or around February 3, 2012.

39. This action is being commenced before the expiration of forty-five days from the date of receipt of the Alkem Notice Letter.

40. In the Alkem Notice Letter, Alkem also notified Plaintiffs that, as a part of its ANDA, Alkem had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the '040 Patent. On information and belief, Alkem submitted ANDA No. 203741 to the FDA containing a certification pursuant

to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '040 Patent is invalid and/or will not be infringed by the manufacture, use, offer for sale, or sale of Alkem's ANDA Products.

41. The use of Alkem's ANDA Products is covered by one or more claims of the '040 Patent.

42. Alkem's filing of ANDA No. 203741 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Alkem's ANDA Products before the expiration date of the '040 Patent is an act of infringement of the '040 Patent, under 35 U.S.C. § 271(e)(2)(A).

43. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Alkem's ANDA Products would infringe one or more claims of the '040 Patent.

44. On information and belief, the use of Alkem's ANDA Products in accordance with and as directed by Alkem's proposed labeling for that product would infringe one or more claims of the '040 Patent.

45. On information and belief, unless enjoined by this Court, Alkem intends to engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Alkem's ANDA Products with its proposed labeling immediately and imminently upon approval of ANDA No. 203741.

46. On information and belief, unless enjoined by this Court, Alkem plans and intends to, and will, actively induce infringement of the '040 Patent when its ANDA No. 203741 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

47. Alkem had knowledge of the '040 Patent when it submitted ANDA No. 203741.

48. On information and belief, Alkem knows that Alkem's ANDA Products and its proposed labeling are especially made or adapted for use in infringing the '040 Patent, and that Alkem's ANDA Products and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, unless enjoined by this Court, Alkem plans and intends to, and will, contribute to the infringement of the '040 Patent immediately and imminently upon approval of ANDA No. 203741.

49. The foregoing actions by Alkem constitute and/or will constitute infringement of the '040 Patent, active inducement of infringement of the '040 Patent, and/or contribution to the infringement by others of the '040 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

50. On information and belief, Alkem acted without a reasonable basis for believing that it would not be liable for infringing the '040 Patent, actively inducing infringement of the '040 Patent, and/or contributing to the infringement by others of the '040 Patent.

51. Unless Alkem is enjoined from infringing the '040 Patent, actively inducing infringement of the '040 Patent, and/or contributing to the infringement of the '040 Patent, Plaintiffs will suffer irreparable injury.

52. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA No. 203741 to be a date which is not earlier than December 17, 2021, the current expiration date of the '040 Patent, or any extension of that expiration date that might arise after the filing of this Complaint.

53. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

A. A declaration that the '040 Patent is valid and enforceable;

B. A judgment that the '040 Patent would be infringed by Indchemie's ANDA Products; that submission of ANDA No. 203828 is an act of infringement of the '040 Patent; and that Indchemie's making, using, offering to sell, selling, marketing, distributing, or importing Indchemie's ANDA Products, or any product or compound that infringes the '040 Patent, prior to the expiration date of the '040 Patent, would infringe, actively induce infringement, and contribute to the infringement of the '040 Patent;

C. An Order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of Indchemie's ANDA No. 203828, or any product or compound that infringes the '040 Patent, shall be a date which is not earlier than December 17, 2021, the current expiration date of the '040 Patent or any extension thereof;

D. An Order permanently enjoining Indchemie, and its affiliates and subsidiaries, and each of their officers, agents, servants and employees, from making, using, offering to sell, selling, marketing, distributing, or importing Indchemie's ANDA Products, or any other product or compound, not colorably different, that infringes the '040 Patent, or inducing or contributing to the infringement of the '040 Patent until after the expiration of the '040 Patent;

E. Damages or other monetary relief, including prejudgment interest, if Indchemie engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or importation of Indchemie's ANDA Products, or any product or compound that infringes the '040 Patent, or the inducement or contribution of the foregoing, prior to the expiration of the '040 Patent;

F. A judgment that the '040 Patent would be infringed by Alkem's ANDA Products; that submission of ANDA No. 203741 is an act of infringement of the '040 Patent; and that Alkem's making, using, offering to sell, selling, marketing, distributing, or importing Alkem's

ANDA Products, or any product or compound that infringes the '040 Patent, prior to the expiration date of the '040 Patent, would infringe, actively induce infringement, and contribute to the infringement of the '040 Patent;

G. An Order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of Alkem's ANDA No. 203741, or any product or compound that infringes the '040 Patent, shall be a date which is not earlier than December 17, 2021, the current expiration date of the '040 Patent or any extensions thereof;

H. An Order permanently enjoining Alkem, and its affiliates and subsidiaries, and each of their officers, agents, servants and employees, from making, using, offering to sell, selling, marketing, distributing, or importing Alkem's ANDA Products, or any other product or compound, not colorably different, that infringes the '040 Patent, or inducing or contributing to the infringement of the '040 Patent until after the expiration of the '040 Patent;

I. Damages or other monetary relief, including prejudgment interest, if Alkem engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, or importation of Alkem's ANDA Products, or any product or compound that infringes the '040 Patent, or the inducement or contribution of the foregoing, prior to the expiration of the '040 Patent;

J. A declaration that this is an exceptional case and an award of attorneys' fees to Plaintiffs pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

K. Plaintiffs' reasonable costs of suit incurred; and

L. Such other and further relief as this Court may deem just and proper.

Dated: March 14, 2012

Respectfully submitted,

s/_Russell E. Cass_____
David T. Pritikin
Russell E. Cass
SIDLEY AUSTIN LLP
1 S. Dearborn Street
Chicago, Illinois 60603
(312) 853-7000
(312) 853-7036 (Fax)
dpritikin@sidley.com
rcass@sidley.com

Attorneys for Plaintiffs Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and Janssen Pharmaceutica N.V.

Of Counsel:

David A. Steffes
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, DC 20005
(202) 736-8000
(202) 736-8711 (Fax)
dsteffes@sidley.com

Bindu Donovan
Todd L. Krause
James Suh
S. Isaac Olson
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, New York 10019
(212) 839-5300
(212) 839-5599 (Fax)
bdonovan@sidley.com
tkrause@sidley.com
james.suh@sidley.com
isolson@sidley.com